



K113399 1/2

DEC 20 2011

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## **Internal Fixation Systems, Inc. 510(k) Summary**

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**Company Name:** Internal Fixation Systems, Inc.  
10100 N.W. 116<sup>th</sup> Way, Suite 18  
Miami, Florida 33178

**Contact Name:** Christopher Endara  
10100 N.W. 116<sup>th</sup> Way, Suite 18  
Miami, Florida 33178  
(305) 884-5993

**Trade Name:** IFS Subtalar Implant

**Common Name:** Bone Fixation Fasteners

**Regulation Name:** Smooth or Threaded Metallic Bone Fixation Fastener

**Regulation Number:** 21 CFR 888.3040

**Regulatory Class:** II

**Device Product Code:** HWC

**Substantially Equivalent Devices:** Nexa Subtalar Arthrorisis Implant (K032902)  
Osteomed Subtalar Implant System (K031155)

**Device Description:** The IFS Subtalar Implant is a one-piece device made of Ti 6Al-4V ELI intended to be implanted into the sinus tarsi of the foot. The implant is designed in 6 diameter and length sizes (7mm through 12mm and 13mm through 18mm, respectively). The implant which is used in the treatment of excessive motion of the talus relative to the calcaneus acts as a spacer for the joint, maintaining the joint space, allowing for range of motion, but limiting excessive pronation.



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Intended Use:	The IFS Subtalar Implant is intended to treat hyperpronated foot and stabilize the subtalar joint. It is intended to block forward, downward and medial displacement of the talus, thus allowing normal subtalar joint motion but blocking excessive pronation and the resulting sequela.
Technological Characteristics Comparison:	The IFS Subtalar Implant is substantially equivalent to the predicate devices with respect to the design, function, and material. The implants have the same overall diameters, lengths, and material composition.
Sterilization Information:	IFS Subtalar Implant will be distributed non-sterile. The devices are sterilized by the end user per the AAMI Guidelines "Good Hospital Practice: Steam Sterilization and Sterility Assurance" and ANSI/AAMI/ISO 11737 guidelines to achieve the Sterility Assurance Level (SAL) of $10^{-6}$ .
Conclusion:	There are no significant differences between the subtalar implant and the other implants as listed in the Substantially Equivalent Devices. The IFS Subtalar Implant and the predicate devices have similar design attributes, material, and intended use thus is substantially equivalent.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration  
10903 New Hampshire Avenue  
Document Mail Center - WO66-G609  
Silver Spring, MD 20993-0002

Internal Fixation Systems, Inc.  
% Mr. Christopher Endara  
10100 N.W. 116<sup>th</sup> Way, Suite 18  
Miami, Florida 33178

DEC 20 2011

Re: K113399  
Trade/Device Name: IFS Subtalar Implant  
Regulation Number: 21 CFR 888.3040  
Regulation Name: Smooth or threaded metallic bone fixation fastener  
Regulatory Class: II  
Product Code: HWC  
Dated: November 7, 2011  
Received: November 17, 2011

Dear Mr. Endara:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical

device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

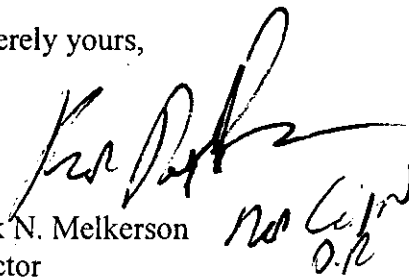
If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to <http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm> for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to

<http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address

<http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,

A handwritten signature in black ink, appearing to read "Mark N. Melkerson", with a stylized flourish at the end. To the right of the signature, there is a handwritten note "no sign" and the date "0.12".

Mark N. Melkerson  
Director  
Division of Surgical, Orthopedic  
and Restorative Devices  
Office of Device Evaluation  
Center for Devices and  
Radiological Health

Enclosure

## Indications for Use

510(k) Number (if known): **K113399**

Device Name: IFS Subtalar Implant

Indications for Use: The IFS Subtalar Implant is intended to treat hyperpronated foot and stabilize the subtalar joint. It is intended to block forward, downward and medial displacement of the talus, thus allowing normal subtalar joint motion but blocking excessive pronation and the resulting sequela.

Prescription Use   X    
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use \_\_\_\_\_  
(Part 21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF  
NEEDED)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

*for Mark Melanson*

(Division Chief)  
Division of Surgical, Orthopedic,  
and Restorative Devices

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